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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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J. Michael Salbaum

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03/25/2008

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EXAMINER

HADDAD, MAHER M

ART UNIT

PAPER NUMBER

1644

MAIL DATE

DELIVERY MODE

03/25/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/754,997	SALBAUM, J. MICHAEL	
	<b>Examiner</b>	<b>Art Unit</b>	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 and 16-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9-15 and 20-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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## RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 1/25/08, is acknowledged.
2. Claims 1-42 are pending.
3. Claims 1-8 and 16-19 stand withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention.
4. Claims 9-15 and 20-42 are under examination as they read on an isolated nucleic acid molecule of SEQ ID NO: 1 encoding Nope polypeptide of SEQ ID NO: 2 and SEQ ID NOs: 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23 and oligonucleotides 300-325, 325-350 and 300-350 as the species.
5. In view of the amendment filed on 1/25/08, only the following rejections are remained.
6. 35 U.S.C. § 101 reads as follows:  
*"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".*
7. Claims 9-15 and 20-42 stand rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and/or substantial asserted utility or a well established utility for the same reasons set forth in the previous Office Actions.

Applicant's arguments, filed 1/25/08, have been fully considered, but have not been found convincing.

Applicant argues that the specification teaches a substantial and specific utility and is clearly distinguishable from the EST's at issue in *In re Fischer*, Case No. 04-1465 (Fed. Cir. Sept. 9, 2005). *In re Fisher* makes it clear that the threshold for utility of a DNA sequence is the identification of a function for the underlying protein-encoding genes. Analysis of the Nope sequence revealed that the protein encoded by the Nope nucleic acid sequence contains four immunoglobulin domains and five fibronectin-type domains, has structural similarity to DCC, Punc and NCAM, and most closely resembles cell adhesion molecules (page 46, lines 8-17). The specification further teaches the function of these structurally related proteins as axonal guidance receptors (page 49, line 22, to page 50, line 7). The specification also teaches the developmental expression of Nope, including its expression in cells of the nervous system (Example II, pages 46-48, in particular page 47, line 27, to page 48, line 16). The specification clearly provides an explicit teaching of a specific, substantial and credible utility of the Nope polynucleotide in that it encodes a protein expressed in the nervous system and that functions as an axonal guidance receptor.

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With regard to the claimed Nope encoding nucleic acids, the specification teaches that the nucleic acid encodes a polypeptide having four immunoglobulin domains and five fibronectin-type domains, both of which are well characterized structural domains (page 46, lines 8-17). In addition, the specification teaches that Nope is related to axonal guidance receptors (page 49, line 22, to page 50, line 3). Furthermore, the specification teaches that Nope is expressed in the nervous system, consistent with its role in axonal guidance. Therefore, the claimed nucleic acids encoding Nope are correlated in the specification with well known structural motifs, proteins with known function, and tissue expression consistent with that function.

It is still the Examiner's position that that structural similarity is not predictive of functional similarity. Functional relatedness is not credible in the face of evidence in the art that structurally related polypeptides in the Ig-like families are frequently dissimilar functionally. The members of the family have different biological activities, but there is no evidence that the claimed compounds would share any one of those different activities. That is, no activity is known to be common to all members of DCC protein. Further, the four immunoglobulin domain and five FnIII repeats of Nope share only 45% amino acid sequence similarity with mouse Punc. In addition, the cytoplasmic domains of NOPE and mouse Punc do not share amino acid sequence similarity. The rejection sets forth that, among related polypeptides in the Ig and FnIII families, structural similarity is not predictive of functional similarity. The immunoglobulin superfamily (IgSF) is a heterogenic group of proteins built on a common fold, called the Ig fold, which is a sandwich of two beta sheets. Although members of the IgSF share a similar Ig fold, they differ in their tissue distribution, amino acid composition, and biological role. Rougon et al (Annu Rev Neurosci. 2003;26:207-38. 2003) teach that immunoglobulin superfamily (IgSF) proteins are implicated in diverse steps of brain development, including neuronal migration, axon pathfinding, target recognition and synapse formation, as well as in the maintenance and function of neuronal networks in the adult. Rougon *et al* illustrate that the complexity of IgSF protein function results from various different levels of regulation including regulation of gene expression, protein localization, and protein interactions. Functional relatedness is not credible in the face of evidence in the art that structurally related polypeptides in the Ig-like families are frequently dissimilar functionally. The members of the family have different biological activities, but there is no evidence that the claimed Nope would share any one of those different activities. That is, no activity is known to be common to all members of DCC protein.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

*The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.*

9. Claims 9-15 and 20-42 stand also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and/or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention for the same reasons set forth in the previous Office Actions.

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10. Claims 10 and 14 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the same reasons set forth in the previous Office Actions.

Applicant's arguments, filed 1/25/08, have been fully considered, but have not been found convincing.

Applicant submits that this rejection has been rendered moot by the amendment to claim 9.

The how to use prong of section 112 incorporates as a matter of law the requirement of 35 U.S.C. § 101 that the specification disclose as a matter of fact a practical utility for the invention. If the application fails as a matter of fact to satisfy 35 U.S.C. § 101, then the application also fails as a matter of law to enable one of ordinary skill in the art to use the invention under 35 U.S.C. § 112. Claim 10 still recites nucleotide sequence modification.

11. No claim is allowed.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen B. O'Hara can be reached on (571) 272-0878. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

March 18, 2008

/Maher M. Haddad/  
Primary Examiner,  
Art Unit 1644